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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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HAYNES BEFFEL & WOLFELD LLP P O BOX 366 HALF MOON BAY, CA 94019			RYCKMAN, MELISSA K	
			ART UNIT	PAPER NUMBER
			3734	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/776,682	Applicant(s) MORALES ET AL.	
	Examiner Melissa Ryckman	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/25/04, 9/12/05, 3/16/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 10, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Nash et al. (U.S. Patent No. 5,242,456).

1. Regarding claim 1 Nash et al. discloses a device for applying clips comprising a shaft (100B), a plurality of clips (Fig. 8) slidably coupled to a tether (36 Fig. 9) the tethered clips delivered from the shaft (col. 24 ll. 4,5), a clip applier near the distal end of the shaft (112, col. 7 ll. 47-52), at least one actuator near the proximal end of the shaft (408) causing the device to advance the clips and activate the clips to secure the clips to the annulus (112, col. 7 ll. 47-52).
2. Regarding claim 2 Nash et al. discloses a device for applying clips comprising a pusher (col. 11 ll. 54) with an actuator (408) for advancing clips, and at least one slot in an inner surface of the shaft for guiding the clips (114A).
3. Regarding claim 3 Nash et al. a device for applying clips comprising a crimping member (col. 7 ll. 47-52).
4. Regarding claim 4 Nash et al. discloses a clip applier where at least one actuator includes means for cinching the tethered clips to reduce the

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circumference of a valve annulus (col. 24 ll. 7-10). The device of Nash et al. is capable of reducing the circumference of a valve annulus.

5. Regarding claim 5 Nash et al. discloses a device for applying clips comprising at least one actuator consisting of a trigger (408), a handle, a plunger, a squeeze-activated device (408), a syringe-grip device, a syringe-grip device and a foot-operated device.

6. Regarding claim 10 Nash et al. discloses a clip applier where the shaft has a minimally invasive incision (col.16 ll. 54).

7. Regarding claim 15 Nash et al. discloses a clip applier wherein a tether selected from the groups consisting of a suture material (col. 8 ll. 65), a Teflon strip, a band, a filament, a wire and a strap.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. (U.S. Patent No. 5,242,456) as stated in claim 1 above, further in view of Northrup, III (U.S. Patent No. 5,760,695).

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9. Regarding claim 6 Nash et al. discloses the claimed invention except the clips do not include at least one eyelet, and a tether has parallel segments passing through at least one eyelet of each clip. However Northrup, III discloses clips with eyelets with a tether passing through at least one eyelet of each clip (Fig. 1 and 4).

It would have been obvious to one of ordinary skill in the art to use clips with eyelets so a tether could be used to change the circumference of the annulus, as it is known to one of ordinary skill in the art that changing the circumference of the valve annulus is a known way of treating certain cardiac diseases.

10. Regarding claim 7 Nash et al. discloses the claimed invention except the clips do not include two eyelets, and a tether has parallel segments passing through both eyelets of each clip. However Northrup, III discloses clips with eyelets with a tether passing through both eyelets of each clip (Fig. 1 and 4).

It would have been obvious to one of ordinary skill in the art to use clips with eyelets so a tether could be used to change the circumference of the annulus, as it is known to one of ordinary skill in the art that changing the circumference of the valve annulus is a known way of treating certain cardiac diseases.

11. Regarding claim 8 Nash et al. disclose a device for applying clips comprising crimping the clips (col. 7 ll. 47-52), however Nash et al. does not disclose a clip with an eyelet, however Northrup, III discloses clips with eyelets (Fig. 1 and 4).

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It would have been obvious to one of ordinary skill in the art to crimp the eyelets, as it is a good way of securing the tether so the tether will not adjust.

12. Claims 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. (U.S. Patent No. 5,242,456) as stated in claim 1 above, further in view of Meade (U.S. Patent No. 6,306,149).

13. Regarding claim 9 Nash et al. discloses the claimed invention except for a curved tip at the end of the shaft. However, Meade discloses a device for applying clips comprising a shaft where the distal end comprising a curved tip (12, Fig. 1).

It would have been obvious to one of ordinary skill in the art curve the tip upwards on the shaft as this can help to guide the clip.

Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. (U.S. Patent No. 5,242,456) as stated in claim 1 above, further in view of Franzier (U.S. Patent No. 6,328,727).

14. Regarding claim 11 Nash et al. discloses the claimed invention except a tether anchor coupled to a tether and carried by the shaft. However Franzier et al. teaches a tethered anchor (Fig. 2) carried by a shaft.

It would have been obvious to one of ordinary skill in the art to provide an anchor for the clips as this will help to keep the placement of the clips in the correct position to prevent loosening which is important as decreasing the circumference of the annulus can help treat cardiac disease.

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15. Regarding claim 12 Nash et al. discloses the claimed invention except does not have a tether anchor with a rivet. However Franzier et al. teaches a tether anchor comprising a rivet (col. 5, ll. 27 Fig. 16).

It would have been obvious to one of ordinary skill in the art include a rivet in the anchor as this can help to attach the suture to the anchor.

16. Regarding claims 13 and 14 Nash et al. discloses a device for applying clips comprising tethered clips that are crimped (col. 7 ll. 47-52), it does not have an anchor, however Franzier et al. teaches a tether anchor (Fig. 2). The placement of the anchor is not mentioned, however it would have been obvious to one of ordinary skill in the art to place the anchor on the last clip or the penultimate clip as to anchor the clips and tether around the annulus.

It would have been obvious to one of ordinary skill in the art to add an anchor to the clip and tether of Nash et al. Securing the tether would have been obvious to one of ordinary skill in the art as motion in the tether would not be desirable as this could cause the tether to loosen or could damage the tissue.

17. Claims 16-22, 26-28, and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. (U.S. Patent No. 5,242,456), in view of Meade (U.S. Patent No. 6,306,149), Northrup, III (U.S. Patent No. 5,760,695) and Johnson (U.S. Patent No. 5,766,240).

18. Regarding claim 16 Nash et al. discloses a device for applying clips comprising a shaft (100B), a clip applicator near the distal end of the shaft (112, col. 7 ll. 47-52), at least one actuator near the proximal end of the shaft (408) causing

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the device to advance the clips and activate the clips to secure the clips to the annulus (112, col. 7 ll. 47-52), and clips are arranged successively on said tether (Fig. 9). Nash et al. does not have a tether with two parallel segments, however Northrup, III teaches a tether having at least two parallel segments, and a plurality of clips which slidably receive both segments of the tether, wherein said clips are arranged successively on said tether (Fig. 4).

It would have been obvious to one of ordinary skill in the art to tether with two parallel segments, as two tethers can make the device more stable which is desirable so the clips won't move causing irritation or loosening of the tether.

19. Regarding claim 17 Nash et al. discloses the claimed invention except does not have a pair of eyelets in the clips, however Northrup, III teaches each clip includes a pair of spaced-apart eyelets, wherein one segment is received in each eyelet of the pair (Fig. 4).

It would have been obvious to one of ordinary skill in the art to use clips with eyelets so a tether could be used to change the circumference of the annulus, as it is known to one of ordinary skill in the art that changing the circumference of the valve annulus is a known way of treating certain cardiac diseases.

20. Regarding claim 18 Nash et al. disclose a device for applying clips comprising crimping the clips (col. 7 ll. 47-52), Nash et al. does not disclose a clip with an eyelet, however Northrup, III discloses clips with eyelets (Fig. 1 and 4).

It would have been obvious to one of ordinary skill in the art to crimp the eyelets as it is a good way of securing the tether so the tether will not adjust.

Regarding claim 19 Nash et al. discloses an annular fastener comprising a plurality of clips (Fig. 8) but does not have a first and second segment for the tether. However, Northrup, III teaches a clip comprising a first and second tether-receiving element (Fig. 4).

It would have been obvious to one of ordinary skill in the art to have a first and second segment as this can help to secure the clips and maintain the correct circumference of the annulus.

21. Regarding claim 20 Nash et al. discloses an annular fastener comprising a terminal clip with is fixed to a leading end of the tether (Fig. 9).

22. Regarding claim 21 Nash et al. discloses an annular fastener with a plurality of clips with at least three clips (Fig. 8).

23. Regarding claim 22 Nash et al. discloses an annular fastener where the clips are crimped (col. 7 ll. 47-52), with a tether receiving elements (Fig. 9).

24. Regarding claim 26 Nash et al. discloses the claimed invention except for a stabilization device, however Northrup, III teaches a stabilization device adapted to capture and immobilize the annulus relative to the remainder of the heart (abstract, ll. 2,14-18).

It would have been obvious to one of ordinary skill in the art to stabilize the device so the device does not move which could cause irritation or loosening. Loosening would be a problem as the circumference of the annulus is important as it can help to treat cardiac disease.

25. Regarding claim 27 and 28 Nash et al. discloses the claimed invention except for a stabilization device, however Johnson teaches a stabilization device

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comprising a pair of rings which are adapted to clamp opposed faces of the annular surface (Fig. 4) and a device that clamps over and under a heart valve (Fig. 4) annulus (the terms over and under only refer to the location of the heart valve).

It would have been obvious to one of ordinary skill in the art to use rings as a stabilization device as the ring would not loosen like a tether and the ring applies pressure to the tethered clips to assure their attachment.

26. Regarding claim 33 and 34 Nash et al. discloses the claimed invention except for a visualization device adapted to directly view a valve annulus in a heart chamber and a visualization device comprising an ultrasonic imaging transducer. However Crowley teaches a visualization device adapted to directly view a valve annulus in a heart chamber (Fig. 30) and a visualization device comprising an ultrasonic imaging transducer (Fig. 3 and 4).

It would have been obvious to one of ordinary skill in the art to include a visualization device at the end of the claimed invention to insure proper installation of the clips during surgery.

27. Regarding claim 35 Nash et al. discloses the claimed invention except for an optical viewing element, however Johnson discloses an optical viewing element (col. 15 ll.44) disposed in a transparent element (col. 5 ll. 11).

It would have been obvious to one of ordinary skill in the art to include an optical viewing element to insure proper installation of the clips during surgery.

28. Regarding claim 36 Nash et al. discloses the claimed invention except for a transparent element comprising a transparent balloon inflatable with a

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transparent inflation medium, however Crowley teaches a transparent balloon inflatable with a transparent inflation medium (col.4 ll.35, col. 17 ll. 6).

It would have been obvious to one of ordinary skill in the art to include a balloon at the end of the element to occlude blood flow, as this is common within the art.

29. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. (U.S. Patent No. 5,242,456) as stated in claim 1 above, further in view of Northrup, III (U.S. Patent No. 5,760,695) and Johnson (U.S. Patent No. 5,766,240).

30. Regarding claim 23 Nash et al. discloses the claimed invention except for a stabilization device, however Northrup, III teaches a stabilization device adapted to capture and immobilize the annulus relative to the remainder of the heart (abstract, ll. 2,14-18).

It would have been obvious to one of ordinary skill in the art to stabilize the device so the device does not move which could cause irritation or loosening. Loosening would be a problem as the circumference of the annulus is important as it can help to treat cardiac disease.

31. Regarding claims 24 and 25 Nash et al. discloses the claimed invention except for a stabilization device, however Johnson teaches a stabilization device comprising a pair of rings which are adapted to clamp opposed faces of the annular surface (Fig. 4) and a device that clamps over and under a heart valve

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(Fig. 4) annulus (the terms over and under only refer to the location of the heart valve).

It would have been obvious to one of ordinary skill in the art to use rings as a stabilization device as the ring would not loosen like a tether and the ring applies pressure to the tethered clips to assure their attachment.

32. Claims 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. (U.S. Patent No. 5,242,456) as stated in claim 1 above, further in view of Crowley (U.S. Patent No. 5,524,630)

33. Regarding claims 29 and 30 Nash et al. discloses the claimed invention except for a visualization device adapted to directly view a valve annulus in a heart chamber and a visualization device comprising an ultrasonic imaging transducer. However Crowley teaches a visualization device adapted to directly view a valve annulus in a heart chamber (Fig. 30) and a visualization device comprising an ultrasonic imaging transducer (Fig. 3 and 4).

It would have been obvious to one of ordinary skill in the art to include a visualization device at the end of the claimed invention to insure proper installation of the clips during surgery.

34. Regarding claim 31 Nash et al. discloses the claimed invention except for an optical viewing element, however Johnson discloses an optical viewing element (col. 15 ll. 44) disposed in a transparent element (col. 5 ll. 11).

It would have been obvious to one of ordinary skill in the art to include an optical viewing element to insure proper installation of the clips during surgery.

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35. Regarding claim 32 Nash et al. discloses the claimed invention except for a transparent element comprising a transparent balloon inflatable with a transparent inflation medium, however Crowley teaches a transparent balloon inflatable with a transparent inflation medium (col.4 ll.35, col. 17 ll. 6).

It would have been obvious to one of ordinary skill in the art to include a balloon at the end of the element to occlude blood flow, as this is common within the art.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

(U.S. Patent No. 5,520,702) Sauer et al. discloses a device for applying a cinch member.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Ryckman whose telephone number is (571)-272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571)-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER